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EXAMINER

FRENEL, VANEL

ART UNIT

PAPER NUMBER

3687

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/609,253	Applicant(s) WALKER ET AL.	
	Examiner VANEL FRENEL	Art Unit 3687	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/23/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5-47,49,50 and 116-125 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,5-47,49,50 and 116-125 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the Appeal Brief filed on 12/23/08. Claims 2, 3, 5-47, 49-50 and 116-125 are pending.

2. Applicant's arguments filed on 12/23/08 have been persuasive, therefore the prior Office Action has been withdrawn and a new Office Action is hereby presented.

3. In view of the Appeal Brief filed on 9/20/06, PROSECUTION IS HEREBY REOPENED as set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 C.F.R 1.111 (if this Office action is non-final) or a reply under 37 C.F.R 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplement appeal brief, but no new amendments, affidavits (37 C.F.R 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 C.F.R 1.193) (b) (2).

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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5. Claims 2-3, 5-47, 49-50 and 116-126 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 2-3, 5-47, 49-50 and 116-126 recite a process comprising the steps of storing, wirelessly communicating a signal, the signal and generating. Based on Supreme Court precedent, a proper process must be tied to another statutory class or transform underlying subject matter to a different state or thing (*Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780,787-88 (1876)). Since neither of these requirements is met by the claim, the method is not considered a patent eligible process under 35 U.S.C. 101. To qualify as a statutory process, the claim should positively recite the other statutory class to which it is tied, for example by identifying the apparatus that accomplished the method steps or positively reciting the subject matter that is being transformed, for example by identifying the material that is being changed to a different state.

Double Patenting

6. Claims 2-3, 49 and 116 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8-9 of U.S. Patent No. 7,366,675 in view of U.S. Patent No. 6,294,999 (Yarin et al). Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the patented claim entirely encompasses the subject matter claims 2-3, 49 and 116. In other words the claims 2-3, 49 and 116 are substantially similar to

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claims 1, 8-9 of '675, except claims 2-3, 49 and 116 of the instant application further recite "the signal including an indication of a number of times that the second container is beyond a range in which the first container is able to communicate with the second container." Yarin discloses a system that includes a housing configured to accommodate a plurality of medicine containers that are adapted to store medicine (Figure 3). At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to include housing to accommodate a plurality of containers. As suggested by Yarin, one would have been motivated to include this feature to track compliance information for multiple regimens from one local source. (col. 3, lines 20-40).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 49-50 and 116-125 are rejected under 35 U.S.C. 102(a) as being anticipated by Reber et al (5,950,632).

As per claim 49, Reber discloses a medicine container comprising:
a medicine storage region adapted to store a medicine (See Reber, Col.7, lines 60-67) and a communication device adapted to wirelessly communicate at least one signal between the medicine container and at least one other medicine container (See

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Reber, Col.7, lines 27-54).

As per claim 50, Reber discloses the medicine container wherein the communication device comprises a transceiver (See Reber, Col.7, lines 55-59).

As per claim 116, Reber discloses a method comprising: obtaining a first container for storing a first medicine (See Reber, Col.7, lines 43- 67), the first container being capable of wirelessly communicating with a second container for storing a second medicine (See Reber, Col.7, lines 43-67); and storing a first medicine in the first container (See Reber,Col.7, lines 43-67).

As per claim 117, Reber discloses the method further comprising: obtaining the second container (See Reber, Col.7, lines 43-67); and storing the second medicine in the second container (See Reber, Col.7, lines 43-67).

As per claim 118, Reber discloses the method further comprising positioning the first container and the second container so that the least container and the second container may communicate (Col.3, lines 2-25; Col.7, lines 28-67).

As per claim 119, Reber discloses the method further comprising receiving a code that indicates that the first container and the second container are positioned so

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that the first container and the second container may communicate (Col.3, lines 2-25; Col.7, lines 28-67).

As per claim 120, Reber discloses the method further comprising providing the received code to at least one party (Col.9, lines 1-4).

As per claim 121, Reber discloses the method wherein the at least one party comprises at least one of a representative of an insurance company, a representative of a medical facility and a representative of a pharmacy (Col.9, lines 1-4).

As per claim 122, Reber discloses the method wherein providing the received code comprises providing an image of the received code (Col.11, lines 1-54).

As per claim 123, Reber discloses the method wherein providing the received code comprises entering the received code during a telephone call (Col.7, lines 28-32).

As per claim 124, Reber discloses the method wherein providing the received code comprises e-mailing the received code (Col.7, lines 5-10).

As per claim 125, Reber discloses the method further comprising obtaining a refill for the first container (Col.13, lines 44-67).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 2-3, 5-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reber et al (5,950,632) in view of de la Huerga (6,529,446) and further in view of Yarin et al. (6,294,999).

As per claim 2, Reber discloses a method for use by a first container that is adapted to store first medicine (Reber; Col.7, lines 43-67), the method comprising: storing information regarding the first medicine (See Reber, Col.7, lines 43-67).

Reber does not explicitly disclose the signal including an indication of a number of times that the second container is beyond a range in which the first container is able to communicate with the second container: and generating at least one code based at least in part on the signal, the at least one code indicating whether at least one party has complied with a schedule for taking the first medicine and the second medicine. However, these features are known in the art, as evidenced by de la Huerga. In

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particular, de la Huerga suggests that the signal including an indication of a number of times that the second container is beyond a range in which the first container is able to communicate with the second container (See de la Huerga, Fig.42, Col.47, lines 11-43; Col.48, lines 10-27); and generating at least one code based at least in part on the signal, the at least one code indicating whether at least one party has complied with a schedule for taking the first medicine and the second medicine (See de la Huerga, Col.52, lines 40-64).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of de la Huerga within the system of Reber with the motivation of providing automated medication container which can convey information to a separate device such as patient's home computer to aid in alerting the patient to take the medication in a timely manner (See de la Huerga, Col.7, lines 60-67). As best understood, the combination of Reber and de la Huerga do not explicitly disclose wirelessly communicating a signal between the first container and a second container the second container adapted to store a second medicine.

However, this feature is known in the art, as evidenced by Yarin. In particular, Yarin suggests that the method having wirelessly communicating a signal between the first container and a second container the second container adapted to store a second medicine (See Fig.3; Yarin, Col.9, lines 21-41).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Yarin within the collective teachings of Reber and de la Huerga with the motivation of facilitating compliance with medication

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regimens, especially complex regimens involving multiple medications (See Yarin, Col.4, lines 12-19).

As per claim 3, Yarin discloses the method wherein wirelessly communicating a signal between the first container and a second container comprises at least one of transmitting information regarding the first medicine from the first container to the second container and receiving information regarding the second medicine from the second container (Yarin, Fig.3; Col.9, lines 21- 41).

As per claim 5, Reber discloses the method further comprising outputting the at least one code to at least one of a representative of an insurance company, a representative of a pharmacy and a representative of a medical facility (Col.6, lines 44-53).

As per claim 6, Reber discloses the method further comprising detecting if the first container and the second container cannot communicate (Col.3, lines 2-25).

As per claim 7, Reber discloses the method further comprising determining if the first container and the second container are separated by a distance that prevents the first container and the second container from communicating (Col.3, lines 2-25).

As per claim 8, Reber discloses the method further comprising determining a time when the first container and the second container are at least initially separated by

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the distance that prevents the first container and the second container from communicating (Col.3, lines 9-25).

As per claim 9, Reber discloses the method further comprising at least one of storing the time and transmitting the time (See Reber, Col.4, lines 16-41).

As per claim 10, Reber discloses the method farther comprising determining a distance between the first container and the second container based on the signal (Col.3, lines 9-25).

As per claim 11, Reber discloses the method further comprising at least one of storing the distance and transmitting the distance (Col.4, lines 4-41).

As per claim 12, Reber discloses the method further comprising determining a change in the distance between the first container and the second container based on the signal (Col.3, lines 9-25).

As per claim 13, Reber discloses the method further comprising at least one of storing the change in the distance and transmitting the change in the distance (Col.4, lines 4-4).

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As per claim 14, Reber discloses the method further comprising tracking a location of at least one of the first and the second containers (Col.5, lines 9-30).

As per claim 15, Reber discloses the method wherein tracking the location of at least one of the first and the second containers comprises tracking the location of the at least one of the first and the second containers with a local positioning system (Co1.13, lines 25-43).

As per claim 16, Reber discloses the method further comprising identifying the location of the at least one of the first and the second containers with the local positioning system (Co1.13, lines 25-43).

As per claim 17, Reber discloses the method further comprising: obtaining information regarding a position of the at least one of the first and the second containers with the local positioning system (Co1.13, lines 25- 43); and determining a distance between the first and the second containers based at least in part on the information (Co1.13, lines 25-43).

As per claim 18, Reber discloses the method further comprising receiving information regarding a schedule for taking at least one of the first medicine and the second medicine (See Abstract, lines 1-6; Col.2, lines 39-67).

As per claim 19, Reber discloses the method further comprising storing the information (Col.2, lines 48-51).

As per claim 20, Reber discloses the method of claim 18 wherein receiving information regarding a schedule for taking the first medicine comprises receiving the information regarding the schedule from at least one of a representative of an insurance company, a representative of a pharmacy, a representative of a medical facility, a representative of a manufacturer of at least one of the first and the second medicines and a party that is to take at least one of the first and the second medicines (Col.8, lines 63-67 to Col.9, line 14).

As per claim 21, Reber discloses the method further comprising storing the first medicine in the first container (Col.5, lines 40-54).

As per claim 22, Reber discloses the method further comprising detecting if a portion of the first medicine has been removed from the first container (Col.9, lines 15-67).

As per claim 23, de la Huerga discloses the method wherein detecting if a portion of the first medicine has been removed from the first container comprises detecting if the first container has been opened or closed (See de la Huerga, Col.53, lines 43-54).

As per claim 24, Reber discloses the method wherein detecting if a portion of the first medicine has been removed from the first container comprises detecting a weight of the first container (Col.9, lines 14-30).

As per claim 25, Reber discloses the method wherein detecting if a portion of the first medicine has been removed from the first container comprises detecting a count of the first medicine (Col.9, lines 14-30).

As per claim 26, Reber discloses the method further comprising at least one of storing information regarding the portion and transmitting the information regarding the portion if the portion has been removed from the first container (Col.5, lines 40-54; Col.11, lines 55-67).

As per claim 27, Reber discloses the method of further comprising detecting if the second medicine has been stored in the second container (Col.5, lines 9-54; Col.11, lines 55-67).

As per claim 28, Reber discloses the method further comprising detecting if a portion of the second medicine has been removed from the second container (Col.5, lines 40-54; Col.8, lines 50-62).

As per claim 29, Reber discloses the method wherein detecting if the portion of the second medicine has been removed from the second container comprises receiving a signal from the second container that indicates that the portion of the second medicine has been removed from the second container (Col.8, lines 50-62).

As per claim 30, Reber discloses the method further comprising at least one of storing information regarding the portion and transmitting the information regarding the portion if the portion has been removed from the second container (Col.11, lines 55-67).

As per claim 31, Reber discloses the method further comprising storing the information regarding the second medicine, the information being stored within the first container (Col.7, lines 47-67).

As per claim 32, Reber discloses the method further comprising determining if the first medicine is incompatible with the second medicine (Col .7, lines 60-67 to Col.8, line 41).

As per claim 33, Reber discloses the method further comprising: detecting if a party attempts to take the first medicine within a predetermined time period of taking the second medicine, and generating a warning if the first medicine is incompatible with the second medicine if the first and second medicines are both taken during the predetermined time period (Col.8, lines 29-67 to Col.9, line 30).

As per claim 34, Reber discloses the method further comprising storing an indicator of the warning (Co1.10, lines 5-40).

As per claim 35, Reber discloses the method further comprising transmitting an indicator of the warning (Co1.10, lines 5-40).

As per claim 36, Reber discloses the method wherein transmitting an indicator of the warning comprises transmitting the indicator of the warning to at least one of a representative of an insurance company, a representative of a pharmacy, a representative of a medical facility and a family member (Col.9, lines 1-14).

As per claim 37, Reber discloses the method further comprising receiving information regarding the second medicine stored within second container (Col.7, lines 47-67).

As per claim 38, Reber discloses the method wherein receiving information regarding the second medicine stored within the second container comprises receiving information transmitted by the second container (Col.7, lines 47- 67).

As per claim 39, Reber discloses the method wherein the first and the second medicines are the same medicine (Col.8, lines 1-41).

As per claim 40, Reber discloses the method wherein at least one of the first and the second containers comprises a micro-needle based device (Col.7, lines 33- 67).

As per claim 41, Reber discloses the method further comprising determining if the first container is positioned so as to communicate with the second container, and if not, attempting to prevent a party from accessing at least one of the first and the second medicines (Col.7, lines 55-67 to Col.8, line 49).

As per claim 42, Reber discloses the method wherein preventing a party from accessing at least one of the first and the second medicines comprises preventing the party from opening at least one of the first and the second containers (Col.7, lines 55-67 to Col.8, line 49).

As per claim 43, de la Huerga discloses the method further comprising tracking a number of times the first container is opened or closed (See de la Huerga, Col.53, lines 43-67).

As per claim 44, de la Huerga discloses the method further comprising tracking a number of times the second container is opened or closed (See de la Huerga, Col.53, lines 43-67).

As per claim 45, de la Huerga discloses the method wherein tracking a number of times the second container is opened or closed comprises: receiving a signal from the second container each time the second container is opened or closed (See de la Huerga, Col.53, lines 43-67); and counting a number of signals received from the second container (See de la Huerga, Col.55, lines 50-67 to Col.56, line 11).

As per claim 46, Reber discloses the method further comprising storing at least a portion of a medical history of a party within the first container (Col.7, lines 60-67 to Col.8, line 41).

As per claim 47, Reber discloses the method further comprising storing information regarding a third medicine in the first container if the first container is refilled with the third medicine (Col.7, lines 60-67 to Col.8, line 41).

Response to Arguments

11. Applicant's arguments filed on 12/23/08 with respect to claims 2-3, 5-47, 49-50, and 116-125 have been considered but they are not persuasive.

(A) At pages 11-28 of the 12/23/08 response, Applicant's argues the features in 12/23/08 are not taught by or suggested by the applied references.

In response, all of the limitations which Applicant disputes as missing in the applied references, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Reber, de laHuerga and or

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Yarin based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action, and incorporated herein. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In addition, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANEL FRENEL whose telephone number is (571)272-6769. The examiner can normally be reached on 6:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Matthew S. Gart can be reached on 571-272-3955. The fax phone number for the organization where this application or proceeding is assigned is 571- 273-8300. Information regarding the status of an application may be obtained from the Patent

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Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vanel Frenel/

Examiner, Art Unit 3687

March 29, 2009